



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

*Rec'd 8/27/02
y/b*

AUG 26 2002

Ms. Susan Y. Campbell
General Counsel
Metagenics
100 Avenida La Pata
San Clemente, California 92673

Dear Ms. Campbell:

This is in response to your letter of July 31, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **Meta-Sitosterol** uses the claim "...may help to maintain healthy blood cholesterol levels by interfering with the absorption of dietary cholesterol from the digestive tract." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product does not establish that the claim is about blood cholesterol levels that are already within normal limits and, therefore, implies that the product is intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease.

The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

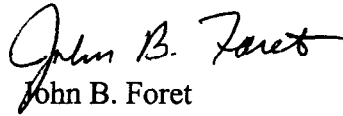
975-0163

LET 635

Page 2 - Ms. Susan Y. Campbell

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, reading "John B. Foret". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

John B. Foret

Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

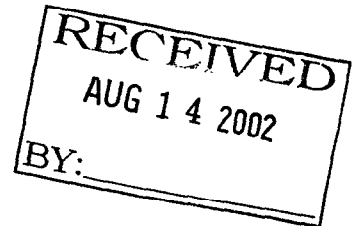
FDA, San Francisco District Office, Office of Compliance, HFR-PA140



July 31, 2002

EXPRESS MAIL NO. EU092434819US

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204



Re: Structure Function Claims/FDA Notification

Dear Sir or Madam:

Enclosed please find an original of the above referenced document prepared in accordance with the proposed regulation 21 C.F.R. Section 101.93.

Should you have any questions or comments, please do not hesitate to contact me.

Sincerely,

Susan Y. Campbell
General Counsel

Enclosure

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100 Avenida La Pata, San Clemente, CA 92673
Tel: 949-366-0818 / 800-692-9400
Fax: 949-369-8695
e-mail: www.metagenics.com

Post Office Box 1729, Gig Harbor, WA 98335
Tel: 253-851-3943 / 800-843-9660
Fax: 253-851-9749
e-mail: www.ultrabalance.com

Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S. C. 343(r)(6) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Metagenics, Inc. with its principal place of business at 100 Avenida la Pata, San Clemente, California 92673, (949) 369-3372, has commenced marketing the following dietary supplements bearing the following statement(s) on the label and/or in the labeling:

METAGENICS BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
Adreset	Cordyceps Mycelium Extract (<i>Cordyceps sinensis</i>) (contains cordycepic acid and adenosine); Asian Ginseng Root Extract (<i>Panax ginseng</i>); Rhodiola Root Extract (<i>Rhodiola rosea</i>)	Adreset features extracts of Asian ginseng, rhodiola, and cordyceps - adaptogens that support an appropriate and healthy response to stress by promoting balanced hypothalamic-pituitary-adrenal axis function. Adreset is designed to enhance stamina and energy, providing exceptional support for those who are stressed and tired.
Cell Protect	Green Tea Leaf Extract (<i>Camellia sinensis</i>); D-Limonene [from sweet orange peel oil (<i>Citrus sinensis</i>)]; Lycopene; Turmeric Rhizome Extract (<i>Curcuma longa</i>)	Cell Protect provides protection for the body's tissues including the breast, prostate, colon, and lung, where it combats destructive free radicals and supports healthy DNA replication and normal cell growth. By combining lycopene with green tea extract, curcumin from turmeric, and D-limonene from citrus peel oil, this formula provides a highly concentrated and targeted blend of tissue-protective phyto-nutrients.
Ceralin	Vitamin A (as mixed carotenoids); Thiamin (as thiamin hydrochloride);	Ceralin provides nutritional support for multiple pathways that impact healthy brain

	Riboflavin; Niacin (as niacinamide); Vitamin B6 (as pyridoxine hydrochloride); Folate (as 5-formyl tetrahydrofolate); Vitamin B12 (as methylcobalamin and Cyanocobalamin); Ginkgo Leaf Extract (<i>Ginkgo biloba</i>); Lutein (from <i>Tagetes erecta</i> flower); Resveratrol (from <i>Polygonum cuspidatum</i> root extract); Acetyl L-Carnitine; N-Acetylcysteine	function including: Resveratrol, lutein, and mixed carotenoids for antioxidant protection; N-acetylcysteine, acetyl-L-carnitine, and thiamin for mitochondrial support; niacinamide and ginkgo for healthy tissue responses and blood circulation; folate and vitamins B6 and B12 to support healthy methylation and homocysteine metabolism.
Intaleve	Chamomile Flower Extract (<i>Matricaria recutita</i>); Peppermint Leaf Oil (<i>Mentha x piperita</i>); English Lavender Flower Oil (<i>Lavandula angustifolia</i>)	Intaleve provides comforting support to the gastrointestinal tract by featuring herbs noted for their antispasmodic and carminative effects. In addition to premium quality peppermint oil, this innovative formula features the added benefits of English lavender oil and chamomile, herbs well known for their relaxing and stress relieving properties.
MetaFiber	Rice bran, beet fiber, oat fiber, apple fiber, cellulose, and d-alpha tocopheryl acetate.	Designed to support normal bowel function and assist in maintaining the balance of intestinal microflora.
Meta-Sitosterol	Calcium, Phosphorus, B-sitosterol, Campesterol, Stigmasterol, Other Phytosterols	Meta-Sitosterol is a naturally derived vegetable preparation featuring a balanced concentrate of phytosterols, which may help to maintain healthy blood cholesterol levels by interfering with the absorption of dietary cholesterol from the digestive tract.
MyoCalm	Calcium (as calcium lactate); Magnesium (as magnesium citrate); Passion Flower (whole flower) (<i>Passiflora incarnata</i>); Passion Flower Extract 4:1 (<i>Passiflora incarnata</i>); Valerian Root (whole root) (<i>Valeriana officinalis</i>); Valerian Root Extract 4:1 (<i>Valeriana officinalis</i>)	MyoCalm is a specialized formula that supplies bioavailable forms of calcium and magnesium, which play a role in muscle contraction and relaxation. These minerals are then blended with extracts of passion flower and valerian root for their added benefits.

MyoCalm P.M.	Calcium (as calcium lactate); Magnesium (as magnesium citrate); Passionflower Flower (<i>Passiflora incarnata</i>); Fassionflower Flower 5.35:1 Extract (<i>Passiflora incarnate</i>) Valerian Root (<i>Valeriana officinalis</i>); Valerian Root 16.15:1 Extract (<i>Valeriana officinalis</i>); Hops Flower, Stobile (<i>Humulus lupulus</i>); Hops Cone 7.5:1 Extract (<i>Humulus lupulus</i>) Kava Root (<i>Piper methysticum</i>)	MycCalm P.M. is a unique, synergistic blend of bioavailable minerals and specialized herbs that is designed to provide comprehensive support for the musculoskeletal system. The components of this formula work in concert to support healthy muscle relaxation, help prevent muscle cramping and spasm, relieve nocturnal leg cramps, promote physical and mental calm, and relieve occasional sleeplessness.
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THE UNDERSIGNED CERTIFIES THAT THE INFORMATION CONTAINED IN THIS NOTICE IS COMPLETE AND ACCURATE AND THAT METAGENICS, INC. HAS SUBSTANTIATION THAT THE STATEMENTS CONTAINED HEREIN ARE TRUTHFUL AND NOT MISLEADING.

Date July 31, 2002

Metagenics, Inc.

BY: Kim Krumhar
Kim Krumhar, Ph.D.
Its Senior Director of Product Development